Avelumab first-line maintenance for advanced urothelial carcinoma: long-term outcomes from JAVELIN Bladder 100 in subgroups defined by response to first-line chemotherapy

B. P. Valderrama,¹ T. Powles,² S. S. Sridhar,³ C. Caserta,⁴ Y. Loriot,⁵ S. Gupta,⁶ J. Bellmunt,⁷ C. N. Sternberg,⁸ J. Wang,⁹ N. Costa,¹⁰ R. J. Laliberte,⁹ A. di Pietro,¹¹ S. H. Park,¹² P. Grivas¹³

¹Department of Medical Oncology, Hospital Universitario Virgen del Rocío, Seville, Spain; ²Barts Cancer Institute, Experimental Cancer Medicine Centre, Queen Mary University of London, St Bartholomew's Hospital, London, UK; ³Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; ⁴Medical Oncology Unit Azienda Ospedaliera S. Maria, Terni, Italy; 5Gustave Roussy, INSERMU981, Université Paris-Saclay, Villejuif, France; ⁶Department of Hematology and Medical Oncology, Cleveland Clinic, Cleveland, OH, USA; ⁷Department of Medical Oncology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA; 8Englander Institute for Precision Medicine, Weill Cornell Medicine, Hematology/Oncology, New York, NY, USA; ⁹Pfizer, Cambridge, MA, USA; ¹⁰Pfizer, Porto Salvo, Portugal; ¹¹Pfizer srl, Milano, Italy; ¹²Sungkyunkwan University Samsung Medical Center, Seoul, Korea; ¹³University of Washington, Fred Hutchinson Cancer Research Center, Seattle Cancer Care Alliance, Seattle, WA, USA



SCOPE



We report long-term outcomes from exploratory analyses in subgroups defined by response to first-line (1L) chemotherapy from the JAVELIN Bladder 100 trial, which compared avelumab 1L maintenance + best supportive care (BSC) vs BSC alone in patients with advanced urothelial carcinoma (aUC) that had not progressed with 1L platinum-containing chemotherapy

CONCLUSIONS



- Long-term follow-up from the JAVELIN Bladder 100 trial (median, ≥38 months in all patients) continues to show prolonged overall survival (OS) and progression-free survival (PFS) with avelumab + BSC vs BSC alone irrespective of best response to 1L chemotherapy (complete response [CR], partial response [PR], or stable disease [SD])
- Long-term safety of avelumab 1L maintenance was consistent across subgroups
- These findings further support avelumab 1L maintenance as standard of care for all patients with aUC that has not progressed with 1L platinum-containing chemotherapy

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Srikala S. Sridhar, <u>srikala.sridhar@uhn.ca</u>

Correspondence:





centers. This trial was sponsored by Pfizer as part of an alliance between Pfizer and the healthcare business of Merck KGaA, Darmstadt, Germany.

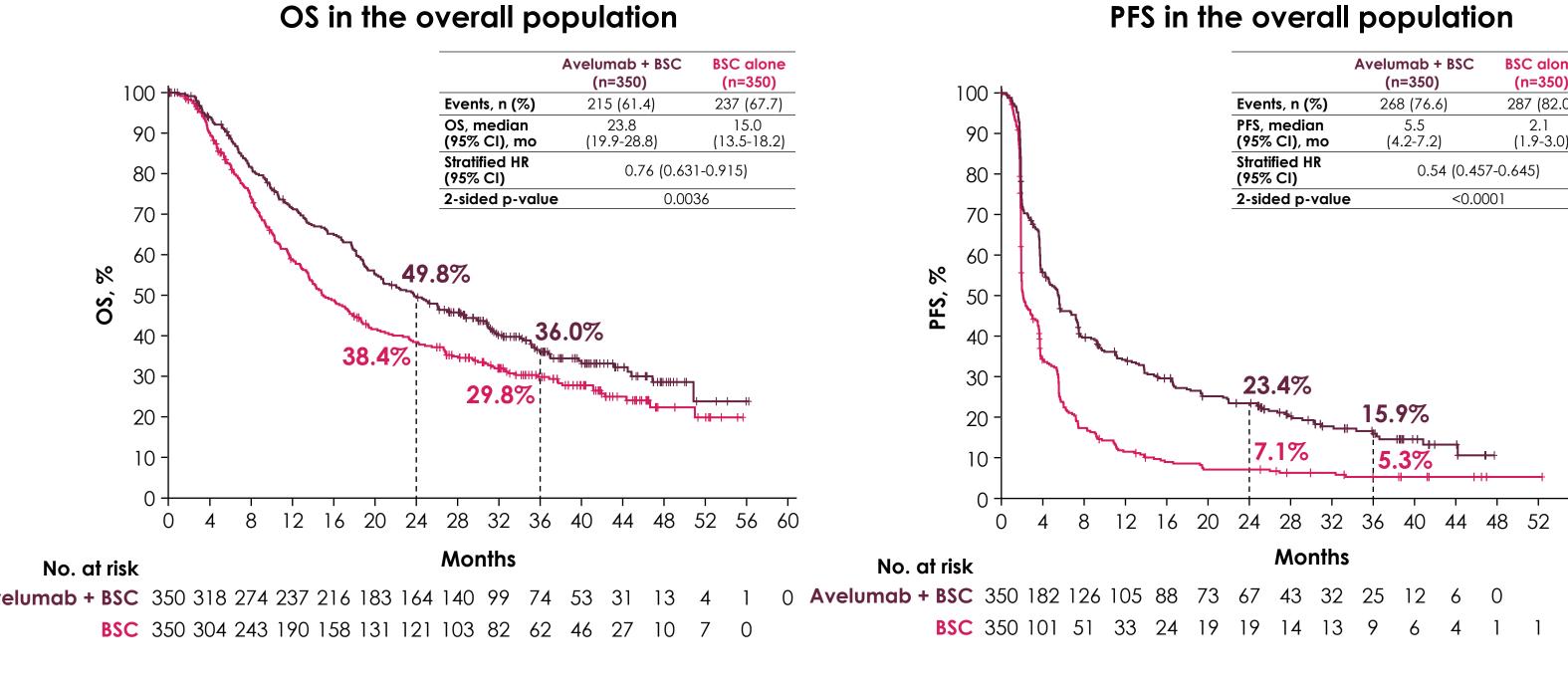
BACKGROUND

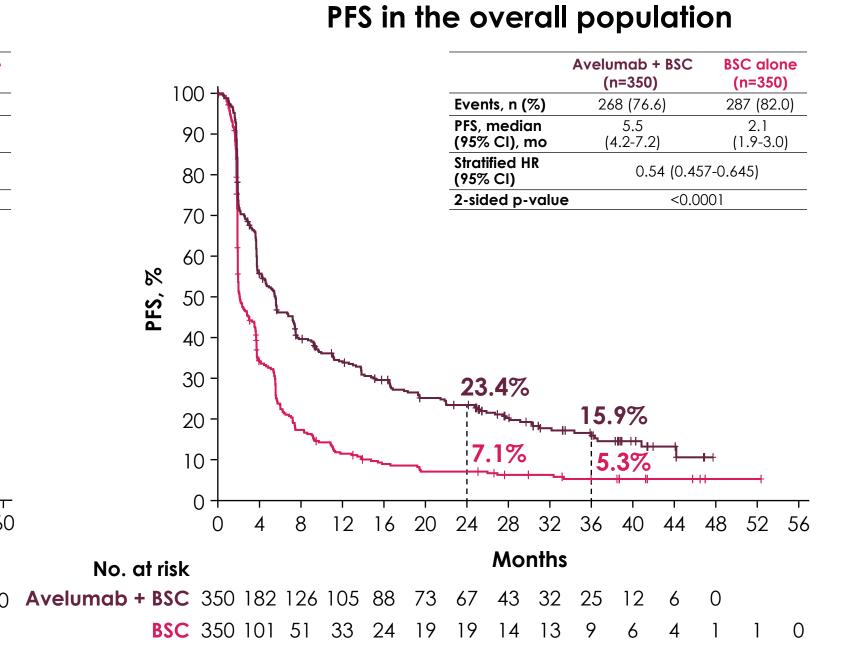
- In the JAVELIN Bladder 100 trial, avelumab 1L maintenance + BSC significantly prolonged OS vs BSC alone in patients with aUC that had not progressed with 1L platinum-containing chemotherapy¹
- In the initial analysis (data cutoff, October 21, 2019), median OS was 21.4 vs 14.3 months, respectively (hazard ratio, 0.69 [95% CI, 0.56-0.86]; 2-sided p=0.001)
- Results from this trial led to the approval of avelumab
- 1L maintenance in various countries worldwide^{2,3} Avelumab 1L maintenance is now recommended as standard of care in international treatment guidelines

based on level 1 evidence⁴⁻⁷

- Long-term results from the trial (data cutoff, June 4, 2021; additional 19 months of median follow-up from the initial analysis) continued to show prolonged OS and PFS with avelumab + BSC vs BSC alone (Figure 1)8 Long-term safety of avelumab 1L maintenance
 - was demonstrated, and no new safety signals BSC, best supportive care; HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

Figure 1. OS and investigator-assessed PFS in the overall population⁸





 The primary endpoint was OS, assessed in all randomized patients and in patients with PD-L1+ tumors

In the phase 3 JAVELIN Bladder 100 trial (NCT02603432),

metastatic UC that had not progressed with 4 to 6 cycles

chemotherapy, patients were randomized 1:1 to receive

avelumab 1L maintenance + BSC or BSC alone (Figure 2)

chemotherapy (CR or PR vs SD) and metastatic site

at start of 1L chemotherapy (visceral vs nonvisceral)

Randomization was stratified by best response to 1L

patients had unresectable locally advanced or

After an interval of 4 to 10 weeks from the end of 1L

of 1L gemcitabine + cisplatin or carboplatin¹

 Secondary endpoints included PFS, which for these long-term follow-up analyses, was based on investigator assessment

METHODS

- In the exploratory analyses presented here, subgroups were defined by best response of CR, PR, or SD after 1L chemotherapy
- Adverse events (AEs) were graded according to the National Cancer Institute CTCAE 4.03

Figure 2. JAVELIN Bladder 100 study design¹

resectable locally

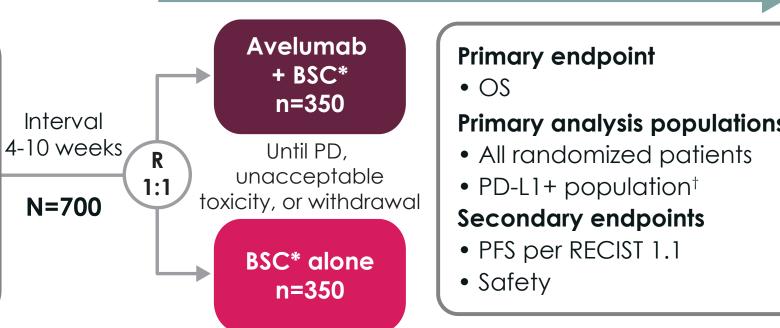
Ivanced or metastatic U

CR, PR, or SD with standard

Cisplatin + gemcitabine

Carboplatin + gemcitabin

chemotherapy (4-6 cycle



All endpoints measured post randomization

 Best response to 1L chemotherapy (CR or PR vs SD) Metastatic site when initiating 1L chemotherapy (visceral vs nonvisceral)

1L, first line; BSC, best supportive care; CR, complete response; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PR, partial response; R, randomization; SD, stable disease; UC, urothelial carcinoma. *BSC (eg, antibiotics, nutritional support, hydration, and pain management) was administered per local practice based on patient needs and clinical judgment; other antitumor therapy was not permitted, but palliative local radiotherapy for isolated lesions was acceptable. Assessed using the Ventana SP263 assay.

RESULTS

were identified

- At data cutoff (June 4, 2021), median follow-up in both arms was ≥38 months
- Across subgroups, the most common reason for treatment discontinuation in both arms was disease progression (Table 1) • OS was prolonged in the avelumab + BSC arm vs BSC alone arm in all subgroups defined by best response to 1L
- chemotherapy (Figure 3)
- Investigator-assessed PFS was also prolonged with avelumab + BSC vs BSC alone across subgroups (Figure 4)
- Compared with patients in the avelumab + BSC arm, more patients in the BSC alone arm received a subsequent second-line anticancer drug therapy (Table 2)

Table 1. Patient disposition

	CR (n=179)		PR (n=326)		SD (n=195)		
	Avelumab + BSC (n=90)	BSC alone (n=89)	Avelumab + BSC (n=163)	BSC alone (n=163)	Avelumab + BSC (n=97)	BSC alone (n=98)	
Study treatment ongoing, n (%)	12 (13.3)	6 (6.7)	21 (12.9)	1 (0.6)	10 (10.3)	3 (3.1)	
Discontinued, n (%)	78 (86.7)	83 (93.3)	142 (87.1)	162 (99.4)	87 (89.7)	95 (96.9)	
Progressive disease	45 (50.0)	69 (77.5)	110 (67.5)	134 (82.2)	54 (55.7)	72 (73.5)	
Adverse event	23 (25.6)	1 (1.1)	14 (8.6)	1 (0.6)	11 (11.3)	0	
Withdrew consent	8 (8.9)	5 (5.6)	4 (2.5)	14 (8.6)	11 (11.3)	12 (12.2)	
Death	0	3 (3.4)	4 (2.5)	6 (3.7)	4 (4.1)	5 (5.1)	
Physician decision	1 (1.1)	2 (2.2)	5 (3.1)	2 (1.2)	5 (5.2)	3 (3.1)	
Global health deterioration	0	0	2 (1.2)	3 (1.8)	1 (1.0)	2 (2.0)	
Other reason*	1 (1.1)	3 (3.4)	3 (1.8)	2 (1.2)	1 (1.0)	1 (1.0)	
Median duration of study treatment (range), months [†]	7.8 (0.5-49.3)	5.5 (0.02-38.7)	5.1 (0.5-49.0)	2.8 (0.02-53.3)	5.8 (0.5-49.7)	2.8 (0.02-37.7	

1L, first line; BSC, best supportive care; CR, complete response; PR, partial response; SD, stable disease

Table 2. Subsequent second-line anticancer therapy

	CR (n=179)		PR (n=326)		SD (n=195)		
	Avelumab + BSC (n=90)	BSC alone (n=89)	Avelumab + BSC (n=163)	BSC alone (n=163)	Avelumab + BSC (n=97)	BSC alone (n=98)	
Discontinued and received subsequent drug therapy, n (%)	45 (50.0)	66 (74.2)	95 (58.3)	117 (71.8)	45 (46.4)	69 (70.4)	
PD-1 or PD-L1 inhibitor	3 (3.3)	36 (40.4)	4 (2.5)	72 (44.2)	4 (4.1)	31 (31.6)	
FGFR inhibitor	1 (1.1)	0	4 (2.5)	3 (1.8)	2 (2.1)	2 (2.0)	
Any other drug*	41 (45.6)	30 (33.7)	87 (53.4)	42 (25.8)	39 (40.2)	36 (36.7)	
Study treatment ongoing, n (%)	12 (13.3)	6 (6.7)	21 (12.9)	1 (0.6)	10 (10.3)	3 (3.1)	

*The most common other drugs received by patients in the avelumab + BSC arm were gemcitabine (n=68), carboplatin (n=35), paclitaxel (n=33), and cisplatin (n=31). The most common other drugs received

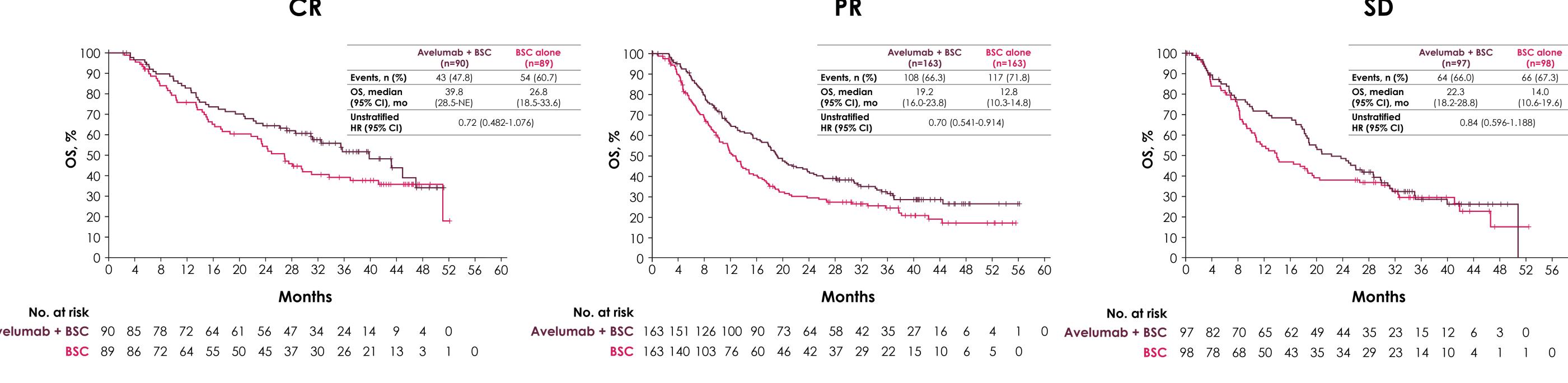
- Long-term safety of avelumab 1L maintenance was consistent across subgroups (**Table 3**)
- The frequency of AEs and treatment-related AEs (TRAEs), including serious AEs and TRAEs, was similar across subgroups
- The frequency of AEs leading to interruption of avelumab was also similar across subgroups; however, a higher proportion of patients in the CR vs PR or SD subgroups had an AE that led to discontinuation
- The most common AEs by best response to 1L chemotherapy are shown in **Table 4**

patients in the BSC alone arm were pembrolizumab (n=58), gemcitabine (n=50), atezolizumab (n=48), carboplatin (n=29), paclitaxel (n=23), and cisplatin (n=29),

Table 3. Summary of long-term safety by best response to 1L chemotherapy

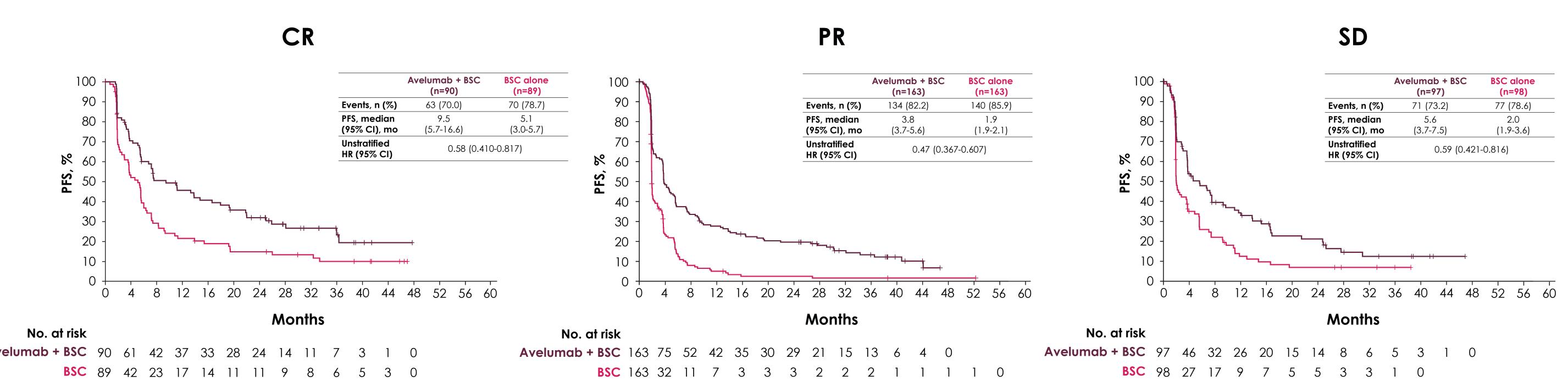
	CR (n=179)		PR (n=319)		SD (n=191)	
Events, n (%)	Avelumab + BSC (n=90)	BSC alone (n=89)	Avelumab + BSC (n=160)	BSC alone (n=159)	Avelumab + BSC (n=94)	BSC alone (n=97)
AE of any grade	88 (97.8)	73 (82.0)	157 (98.1)	121 (76.1)	93 (98.9)	76 (78.4)
Grade ≥3 AE	46 (51.1)	15 (16.9)	83 (51.9)	43 (27.0)	56 (59.6)	31 (32.0)
TRAE of any grade	74 (82.2)	3 (3.4)	126 (78.8)	1 (0.6)	69 (73.4)	2 (2.1)
Grade ≥3 TRAE	21 (23.3)	0	27 (16.9)	0	19 (20.2)	0
Serious AE	26 (28.9)	18 (20.2)	45 (28.1)	28 (17.6)	34 (36.2)	26 (26.8)
Serious TRAE	12 (13.3)	0	12 (7.5)	0	11 (11.7)	0
AE leading to interruption of avelumab	43 (47.8)	_	66 (41.3)	_	47 (50.0)	_
AE leading to discontinuation	21 (23.3)	0	16 (10.0)	0	12 (12.8)	0
TRAE leading to discontinuation	20 (22.2)	0	12 (7.5)	0	8 (8.5)	0
AE leading to death	0	5 (5.6)	4 (2.5)	11 (6.9)	3 (3.2)	8 (8.2)
TRAE leading to death	0	0	2 (1.3)	0	0	0
IRR of any grade	15 (16.7)	0	42 (26.3)	0	18 (19.1)	0

Figure 3. OS by best response to 1L chemotherapy



1L, first line; BSC, best supportive care; CR, complete response; HR, hazard ratio; NE, not estimable; OS, overall survival; PR, partial response; SD, stable disease

Figure 4. Investigator-assessed PFS by best response to 1L chemotherapy



1L, first line; BSC, best supportive care; CR, complete response; HR, hazard ratio; PFS, progression-free survival; PR, partial response; SD, stable disease.

Table 4 Most common AFs by best response to 11 chemotherany

1L, first line; AE, adverse event; BSC, best supportive care; CR, complete response; PR, partial response; SD, stable disease.

Events, n (%)	CR (n=179)				PR (n=319)				SD (n=191)				
	Avelumab + BSC (n=90) BSC		BSC alone (ı	BSC alone (n=89)		Avelumab + BSC (n=160)		BSC alone (n=159)		Avelumab + BSC (n=94)		BSC alone (n=97)	
	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3	
Any AE	88 (97.8)	46 (51.1)	73 (82.0)	15 (16.9)	157 (98.1)	83 (51.9)	121 (76.1)	43 (27.0)	93 (98.9)	56 (59.6)	76 (78.4)	31 (32.0)	
Arthralgia	21 (23.3)	0	12 (13.5)	0	27 (16.9)	2 (1.3)	9 (5.7)	1 (0.6)	20 (21.3)	0	9 (9.3)	0	
Pruritus	20 (22.2)	1 (1.1)	1 (1.1)	0	26 (16.3)	0	3 (1.9)	0	18 (19.1)	0	2 (2.1)	0	
Asthenia	19 (21.1)	0	3 (3.4)	0	32 (20.0)	0	8 (5.0)	2 (1.3)	11 (11.7)	0	9 (9.3)	2 (2.1)	
Diarrhea	19 (21.1)	1 (1.1)	10 (11.2)	1 (1.1)	25 (15.6)	1 (0.6)	5 (3.1)	0	17 (18.1)	0	3 (3.1)	0	
Fatigue	16 (17.8)	0	5 (5.6)	0	32 (20.0)	3 (1.9)	9 (5.7)	1 (0.6)	17 (18.1)	3 (3.2)	10 (10.3)	1 (1.0)	
Pyrexia	14 (15.6)	0	3 (3.4)	0	23 (14.4)	0	7 (4.4)	0	19 (20.2)	1 (1.1)	3 (3.1)	0	
Urinary tract infection	12 (13.3)	3 (3.3)	11 (12.4)	3 (3.4)	28 (17.5)	6 (3.8)	14 (8.8)	3 (1.9)	21 (22.3)	6 (6.4)	12 (12.4)	3 (3.1)	
Back pain	10 (11.1)	2 (2.2)	7 (7.9)	1 (1.1)	38 (23.8)	1 (0.6)	17 (10.7)	4 (2.5)	11 (11.7)	1 (1.1)	12 (12.4)	3 (3.1)	
Constipation	10 (11.1)	0	11 (12.4)	0	33 (20.6)	1 (0.6)	14 (18.8)	0	17 (18.1)	1 (1.1)	9 (9.3)	0	
Anemia	7 (7.8)	1 (1.1)	5 (5.6)	0	21 (13.1)	4 (2.5)	11 (6.9)	6 (3.8)	16 (17.0)	9 (9.6)	8 (8.2)	4 (4.1)	

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The effect of response to chemotherapy on outcomes in people with advanced urothelial cancer who took part in a study of avelumab as maintenance treatment



The full title of this abstract is: Avelumab first-line (1L) maintenance for advanced urothelial carcinoma (aUC): Long-term outcomes from JAVELIN Bladder 100 in subgroups defined by response to 1L chemotherapy

Please note this summary only contains information from the scientific abstract:



Date of summary: June 2022

View scientific abstract

For more information on this study, go to: https://clinicaltrials.gov/ct2/show/NCT02603432



Medical terms pronunciations

Avelumab <a-VEL-yoo-mab>

Urothelial <YOOR-oh-THEE-lee-ul>

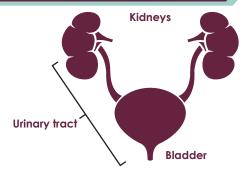
What are the key takeaways from this study?

- The JAVELIN Bladder 100 study showed that avelumab maintenance treatment, which is given after first-line chemotherapy, helped people with advanced urothelial cancer live longer than people who were not treated with avelumab
 - A plain language summary of results from the JAVELIN Bladder 100 study is available at this link
- For this summary, researchers looked at the long-term results from the study. This was when everyone had been studied for at least 2 years after starting the study treatment
- Researchers looked at whether long-term results were affected by how a person's cancer had responded to chemotherapy (disappeared, shrunk, or stopped growing)
- They found that people who were treated with avelumab maintenance are still living longer than those not treated with avelumab. This was found no matter if their cancer had disappeared, shrunk, or stopped growing with first-line chemotherapy
- Safety results with avelumab maintenance treatment were similar for people whose cancer had disappeared, shrunk, or stopped growing with first-line chemotherapy
- These results further support the use of avelumab maintenance treatment as a standard treatment for all people with advanced urothelial cancer that does not get worse with first-line chemotherapy

What did this study look at?

What is advanced urothelial cancer?

- Urothelial cancer is a cancer that develops in the urinary tract
- The urinary tract contains the parts of the body that move urine from the kidneys to the outside of the body. It includes:
 - The bladder
 - The inner part of the kidneys
 - Tubes that connect the kidneys to the bladder and the bladder to the outside of the body
- Urothelial cancer is called advanced when it has spread outside of the urinary tract



What did this study look at? (continued)

How is advanced urothelial cancer treated?

- Chemotherapy is often the first main treatment given to people with advanced urothelial cancer. This is called first-line treatment
- Although the cancer may get better with chemotherapy at first, it will usually start growing again
- If a person's cancer stops growing or shrinks with first-line chemotherapy, they may receive a different treatment instead of waiting for the cancer to grow back again. This is called maintenance treatment. It aims to stop the cancer from getting worse or coming back

What is avelumab?



Avelumab is a type of immunotherapy. Immunotherapy can help the body's immune system find and destroy cancer cells. Avelumab is given as a drip (infusion) into a vein for about an hour once every 2 weeks



Results from the JAVELIN Bladder 100 study have shown that avelumab maintenance treatment can help people with advanced urothelial cancer live longer



Avelumab is the only approved maintenance treatment available for people with advanced urothelial cancer that has stopped growing or shrunk with first-line chemotherapy

What is the JAVELIN Bladder 100 study?

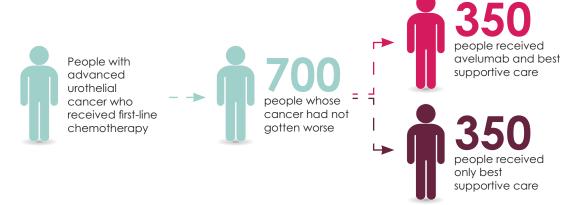
- The JAVELIN Bladder 100 study looked at avelumab maintenance treatment in people with advanced urothelial cancer in various countries worldwide
- All people taking part in the study had received first-line chemotherapy, and their cancer had disappeared, shrunk, or stopped growing. They were put into 2 treatment groups:
 - Treatment group 1 received avelumab maintenance treatment plus best supportive care. Best supportive care includes treatments that help to manage symptoms but do not affect the cancer
 - Treatment group 2 received only best supportive care
- Researchers found that, on average, people who were treated with avelumab plus best supportive care lived longer than people who received only best supportive care
- More results from the JAVELIN Bladder 100 study were collected when everyone had been studied for at least 2 years after starting treatment
 - These results showed that people who received avelumab plus best supportive care continued to live longer, on average, than those who received only best supportive care

What did the researchers want to find out?

Researchers wanted to look at long-term results from the JAVELIN Bladder 100 study. They wanted to see if avelumab maintenance treatment was still helping people with urothelial cancer to live longer, no matter if their cancer had disappeared, shrunk, or stopped growing after first-line chemotherapy

What happened during the study?

Who took part in the study?



- Researchers collected results after everyone had been studied for at least 2 years after starting treatment. This
 was in June 2021
- On average, people in both treatment groups had been studied for at least 38 months

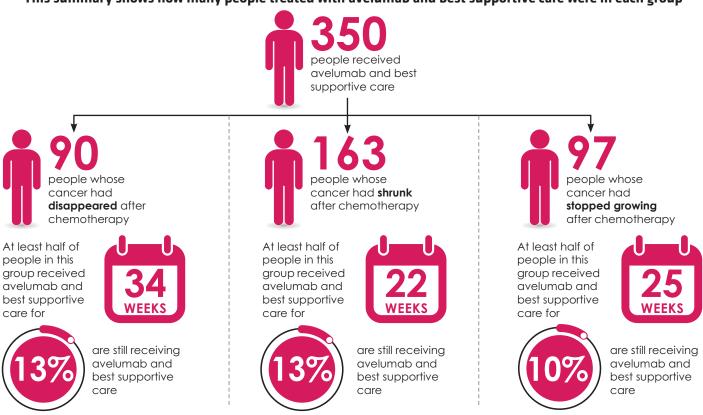
What did the researchers look at?

- Researchers looked at different groups of people, based on how their cancer responded to first-line chemotherapy (disappeared, shrunk, or stopped growing)
- Researchers looked at the following in both treatment groups:
 - How long people lived
 - How long people lived without their cancer getting worse
 - For people who stopped receiving study treatment, how many people then received a different treatment
 - Side effects

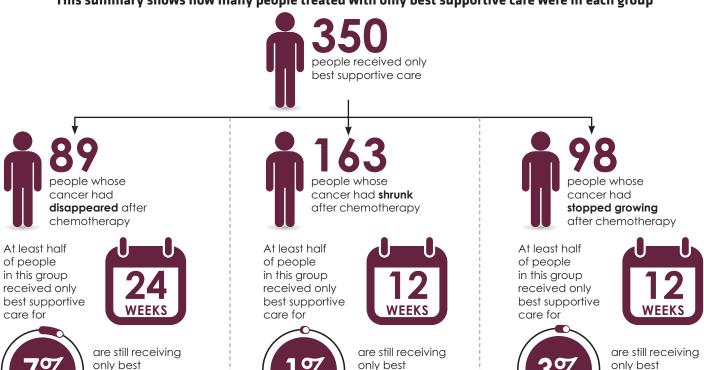
What were the results of the study?

supportive care

This summary shows how many people treated with avelumab and best supportive care were in each group



This summary shows how many people treated with only best supportive care were in each group



supportive care

supportive care

What were the results of the study? (continued)

This summary shows how long at least half of people in the following groups lived

Avelumab and best supportive care

People whose cancer had disappeared after chemotherapy

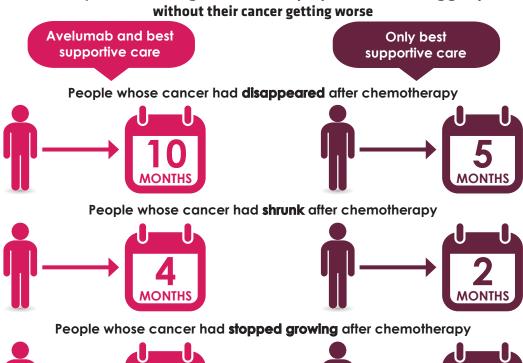
People whose cancer had shrunk after chemotherapy

People whose cancer had shrunk after chemotherapy

People whose cancer had stopped growing after chemotherapy

People whose cancer had stopped growing after chemotherapy

This summary shows how long at least half of people in the following groups lived without their cancer getting worse



What were the results of the study? (continued)

This summary shows how many people received a different treatment after stopping study treatment

Avelumab and best supportive care

Only best supportive care

People whose cancer had **disappeared** after chemotherapy





People whose cancer had **shrunk** after chemotherapy





People whose cancer had **stopped growing** after chemotherapy





This summary shows how many people in the following groups had severe* side effects

Avelumab and best supportive care Only best supportive care

People whose cancer had **disappeared** after chemotherapy





People whose cancer had **shrunk** after chemotherapy





People whose cancer had **stopped growing** after chemotherapy





*A side effect is considered "severe" when it limits daily activities such as bathing and dressing, is disabling or is medically significant, or could be life-threatening, needs hospital care, or causes lasting problems

What were the main conclusions reported by the researchers?

- Long-term results from the JAVELIN Bladder 100 study show that people with advanced urothelial cancer continue to live longer, on average, with avelumab maintenance treatment plus best supportive care than with only best supportive care. This was found no matter if their cancer had disappeared, shrunk, or stopped growing after first-line chemotherapy
- These results further support the use of avelumab maintenance as a standard treatment for all people with advanced urothelial cancer that does not get worse with first-line chemotherapy

Disclaimers

Avelumab is approved to treat the condition that is discussed in this summary. This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study. This study described is still ongoing, therefore the final outcomes of this study may differ from the outcomes described in this summary.

Who sponsored this study?

Pfizer 235 East 42nd Street New York, NY 10017, USA Phone (United States): +1 212-733-2323 The healthcare business of Merck KGaA, Darmstadt, Germany Frankfurter Strasse 250 Darmstadt, 64293, Germany Phone (Germany): +49 6151 720

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Where can I find more information?

For more information on this study, please visit: 2022 ASCO Annual Meeting Scientific Abstract https://clinicaltrials.gov/ct2/show/NCT02603432

For more information on clinical studies in general, please visit: https://www.clinicaltrials.gov/ct2/about-studies/learn https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html

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